K123764

page 1 of 4

5- 510(k) Summary

JAN 31 2013

OCULOPLASTIK

200, rue Sauvé ouest, Montreal, Quebec H3L 1Y9 Canada
Tel (514) 381-3292 Fax (514) 381-1164 Toll-free Tel (888) 381-3292 Fax (800) 879-1849

Jan-16, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

RE: Premarket notification -- Traditional 510(k)

Device name:	Durette ocular implant
Regulation number:	21 CFR 886.3320
Regulatory Class:	Class II
Product code:	HPZ
Establishment reg:	8022166
Contact person:	Sylvain Desrosiers, QM (514) 381-3292 sdesrosiers@oculoplastik.com

To the reviewer:

This is a submission for a 510(k) for the Durette Implant, which were previously cleared by FDA in 2008 (K073293). The basis for this submission is change of welding process, packaging, and labeling. The predicate device was welded using a liquid that was remaining in a dry form after welding; the new process does not require that liquid anymore. The proposed packaging is simpler and clearer for the user. The instructions for use (labeling) has been revised to minimize risk for the user. According to guidance "Deciding When to submit a 510(k) for a Change to an Existing Device" (CDRH, 1997), we determined that this change must be submitted to FDA prior to market in USA (paragraph C3). This change does not affect the indication for use, and does not alter the fundamental scientific technology of the device.

As there is no addition of any other component, the Durette implant is 100% made of acrylic clearing any possible biocompatibility issue. The previous 510(k) submission K073293 was cleared based on our own implants made of the same material grade.

This new welding process has been validated to ensure safety and effectiveness over a long period of time.

Indication for use

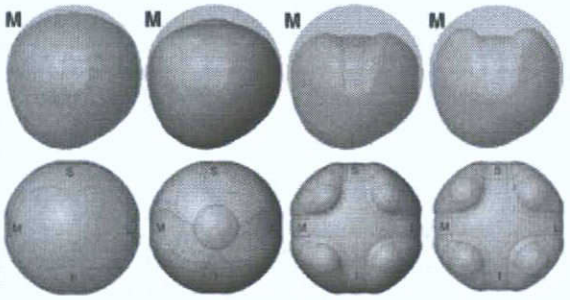
The Durette ocular acrylic (PMMA) implants in 4 models are permanent implants that occupy the eye cavity when it becomes necessary to surgically remove the eye (enucleation), the contents of the eye sac (evisceration), or space left after the removal of another ocular implant (used as a secondary implant). It is used to replace volume and to impart motion and stability to the eventual ocular prosthesis.

Description

The Durette implant is a quasi-spherical ocular implant made in 4 models for variations in anterior surface. Each has a permanent smooth surface and many tunnels to allow direct suturing of the muscles. These 20 interconnected tunnels, all situated in the anterior 3rd of the implant, allow tissue integration or ingrowth to help stabilize the implant. Each has an off-center elongation. Please refer to Article published in the Journal of Ophthalmic Prosthetics and AAO_ASO Joint Scientific Session for more complete explanations on the Durette implant.

Device comparison table identifying relevant similarities and differences

Areas	Predicate Durette implant (laser welding)	Durette implant (ultrasonic welding)
510(k) number	K073293	K123764
FDA Product Class	Class II	Same
Intended use	Enucleation, evisceration and secondary implantation	Same
Indications for use	Birth defects and diseases (cancer, glaucoma,retinal detachment, Etc.) or trauma and ocular socket complications.	Same
Target population	Total population	Same
Anatomical sites	Ocular	Same
Where used	Hospitals and clinics	Same
Compatibility with the environment and other devices	Compatible	Same
Human factors	Used by Ophthalmologists. Permanent and safe implants	Same
Materials	PMMA and liquid for welding	PMMA only.

Design		Same
Biocompatibility	PMMA is biocompatible. The liquid for welding is documented biocompatible.	PMMA is biocompatible. No other component.
Sterility	Sold non-sterile	Same
Performance	Effective and safe. No performance standards applicable to SPHERE, EYE IMPLANT has been assigned by FDA.	Same
Size Range	4 models (1, 2, 3, 4) 6 sizes (16, 18, 19, 20, 21, 22 mm)	4 models (1, 2, 3, 4) 1 size (20 mm)
Chemical safety	PMMA is well documented in ophthalmology	Same
Mechanical safety	Solid devices	Same
Energy used and/or delivered	No energy involved for this type of procedure.	Same
Standards met	None	ISO 10993-5 ISO 10993-7 ISO 11135-1 ISO 14971 ISO 15223-1 AAMI ST72 AAMI ST81
Electrical safety	No electricity involved for this type of procedure.	Same
Thermal safety	Not applicable	Same
Radiation safety	No radiation involved for this type of procedure.	Same
Color additives	Non applicable. No color additives used in the manufacturing process.	Same
Software	Non applicable. No software involved for this device.	Same

Discussion of the nonclinical tests submitted

We are providing assurance that our manufacturing process yields a product within specifications (e.g., bioburden, endotoxin) by the tests performed on the finished product. The device (Durette implant) is a single use device sold Non Sterile. Since it is new and sold non sterile, we include instructions as to how it should be processed to become patient ready (handling and sterilization).

The IFU recommends only sterilization by ethylene oxide (EO), and are based on sterilization

validation for Durette implant. Selected parameters conform with AAMI TIR12:2010.

Conclusion

Based on the proposed changes and results of nonclinical tests, this device has been determined as substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2013

Oculo Plastik, Inc.
% Mr. Sylvain Desrosiers
Quality Manager
200, Rue Sauvé Ouest
Montréal, Québec
Canada H3L 1Y9

Re: K123764
Trade/Device Name: Durette Implant
Regulation Number: 21 CFR 886.3320
Regulation Name: Sphere, Eye Implant
Regulatory Class: Class II
Product Code: HPZ
Dated: December 4, 2012
Received: December 7, 2012

Dear Mr. Desrosiers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K123764

4- Indications for Use

510(k) Number (if known):

Device Name: **Durette Implant**

The Durette ocular acrylic (PMMA) implants in 4 models are permanent implants that occupy the eye cavity when it becomes necessary to surgically remove the eye (enucleation), the contents of the eye sac (evisceration), or space left after the removal of another ocular implant (used as a secondary implant). It is used to replace volume and to impart motion and stability to the eventual ocular prosthesis.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K123764